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Primary measures of dependence among menthol compared to non-menthol cigarette smokers in the United States



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ABSTRACT

Previously published studies provide somewhat inconsistent evidence on whether menthol in cigarettes is associated with increased dependence. The National Health and Nutrition Examination Survey, National Survey on Drug Use and Health, National Health Interview Survey, and Tobacco Use Supplement to the Current Population Survey collect data on current cigarette type preference and primary measures of dependence, and thus allow examination of whether menthol smokers are more dependent than nonmenthol smokers. Analyses based on combined data from multiple administrations of each of these four nationally representative surveys, using three definitions for current smokers (*i.e.*, smoked $\geqslant 1$ day, $\geqslant 10$ days and daily during the past month), consistently demonstrate that menthol smokers do not report smoking more cigarettes per day than non-menthol smokers. Moreover, two of the three surveys that provide data on time to first cigarette after waking indicate no difference in urgency to smoke among menthol compared to non-menthol smokers, while the third suggests menthol smokers may experience a greater urgency to smoke; estimates from all three surveys indicate that menthol versus non-menthol smokers do not report a higher Heaviness of Smoking Index. Collectively, these findings indicate no difference in dependence among U.S. smokers who use menthol compared to non-menthol cigarettes.

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1. Introduction

Measures of cigarette dependence, to varying degrees, correlate with and are predictive of successful smoking cessation; identifying such measures can help target smoking cessation interventions. The Fagerström Test for Nicotine Dependence (FTND; Heatherton et al., 1991) is among the most widely studied composite measures of cigarette dependence, with much of the predictive validity of this measure based on two of its items, *i.e.*, number of cigarettes smoked per day and time to first cigarette after waking. Another composite measure of cigarette dependence, the Heavi-

ness of Smoking Index (HSI; Kozlowski et al., 1994; Heatherton et al., 1989), integrates these two primary measures into a single scale. Both of these composite measures, as well as number of cigarettes smoked per day and time to first cigarette after waking have been shown to predict quitting success (e.g., Baker et al., 2007). Nonetheless, the predictive validity of these dependence measures may have declined in recent years, as restrictions on smoking have become more common. For example, restrictions on smoking in workplaces and other public spaces may have reduced, on average, numbers of cigarettes smoked per day; and, restrictions on smoking at home may have increased times to first cigarette after waking (Baker et al., 2007).

This paper assesses the literature examining cigarette dependence among smokers who use menthol compared to non-menthol cigarettes, based on primary (*i.e.*, number of cigarettes smoked per day, time to first cigarette after waking) and composite measures. Studies were identified by searching the U.S. National Library of Medicine's PubMed database, using the terms "menthol" and "cigarette" to identify pertinent literature (1990 to present). Articles were screened for relevance to menthol cigarette use and dependence, with those that provide data on this outcome measure

Abbreviations: FTND, Fagerström Test for Nicotine Dependence; HSI, Heaviness of Smoking Index; NHANES, National Health and Nutrition Examination Survey; NHIS, National Health Interview Survey; NSDUH, National Survey on Drug Use and Health; NYTS, National Youth Tobacco Survey; TUS-CPS, Tobacco Use Supplement to the Current Population Survey.

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and its potential association with menthol smoking further reviewed and evaluated. A synthesis of the inferences that can be drawn from these studies is provided.

For the current review, greater consideration is placed on those studies that are based on nationally representative samples and that provide analyses that appropriately control for covariates to minimize the potential for bias and confounding. Studies that are based on non-representative samples and present analyses that are not adjusted for covariates are potentially informative, but should not be given as much consideration as appropriately controlled studies based on nationally representative populations. Accordingly, findings from studies that are based on nationally representative samples and/or adjust for covariates are discussed, while those studies that are neither based on nationally representative samples nor adjust for potential confounders are referenced only.

In addition to the literature review, information is provided from original analyses that examine primary and composite measures of dependence among menthol compared to non-menthol cigarette smokers, based on data from four U.S. government surveys (refer to Section 2).

1.1. Number of cigarettes smoked per day

Twelve studies potentially provide evidence on whether menthol compared to non-menthol cigarette use affects dependence; however, nine of these studies present analyses that are based on non-representative populations and that do not adjust for covariates (Brinkman et al., 2012; Brody et al., 2013; Collins and Moolchan, 2006; Gandhi et al., 2009; Hyland and Kasza, unpublished; Okuyemi et al., 2004, 2003; Pletcher et al., 2006; Rosenbloom et al., 2012).

Two of the remaining three studies present estimates of numbers of cigarettes smoked per day among menthol compared to non-menthol smokers based on data from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS). Lawrence et al. (2010) examine data from the 2003 and 2006/07 survey administrations, and present analyses that adjust for demographic and smoking behavior variables. Findings from these analyses indicate that, overall, current menthol cigarette use is statistically associated with smoking fewer cigarettes per day (≥20 cigarettes per day; OR: 0.84, 95% CI: 0.74–0.96; p < 0.05); statistical associations are not observed when stratifying by gender or race/ethnicity. In a separate analysis of the same combined survey years, Fagan et al. (2010) present unadjusted estimates suggesting that daily menthol smokers report smoking statistically fewer cigarettes per day (13.05 versus 15.01, p < 0.01) compared to non-menthol smokers. The last of the three studies provides estimates for numbers of cigarettes smoked per day among menthol compared to non-menthol smokers based on data from the 2005 National Health Interview Survey (NHIS) (Stahre et al., 2010). Unadjusted analyses suggest that current and former (i.e., past-year quitters) menthol smokers report smoking statistically fewer cigarettes per day compared to non-menthol smokers (e.g., 14.6 versus 17.5 among current smokers, p < 0.001).

Thus, three studies (Fagan et al., 2010; Lawrence et al., 2010; Stahre et al., 2010) provide estimates from two nationally representative populations to suggest that menthol smokers overall report smoking statistically fewer cigarettes per day compared to non-menthol smokers; however, only one of these studies (Lawrence et al., 2010) presents analyses that adjusted for covariates.

1.2. Time to first cigarette after waking

In terms of time to first cigarette after waking, eleven studies potentially provide evidence on menthol compared to non-men-

thol smokers, with six of those studies presenting analyses that are neither based on nationally representative samples nor adjusted for covariates (Collins and Moolchan, 2006; D'Silva et al., 2012; Hyland and Kasza, unpublished; Muscat et al., unpublished; Okuyemi et al., 2003; Rosenbloom et al., 2012).

Two of the remaining five studies are based on non-representative samples, but do provide estimates for time to first cigarette after waking that adjust for covariates. Among a population of treatment-seeking smokers, increased night waking to smoke is suggested to be statistically associated with shorter time to first cigarette and menthol cigarette use (Bover et al., 2008); however, no comparison is made between menthol and non-menthol smokers with regard to time to first cigarette. Data from a communitybased cross-sectional study of smokers (Muscat et al., 2009) suggest no statistical association between menthol cigarette use and a shorter time to first cigarette (≤30 min after waking: OR: 2.1. 95% CI: 0.96–3.8): likewise, there is no statistical association between menthol cigarette use and high FTND score (OR: 1.1, 95% CI: 0.6-2.0) or heavy smoking (OR: 0.8, 95% CI: 0.5-1.4). The generalizability of findings from either study to U.S. smokers overall would likely be limited.

The remaining three studies present estimates for time to first cigarette after waking among menthol compared to non-menthol smokers based on either very large or nationally representative samples. Adjusted analyses of baseline data from a community-based intervention trial for smoking cessation (Hyland et al., 2002) indicate that menthol cigarette smokers are statistically less likely to report smoking within 10 min of waking compared to non-menthol smokers. Although the use of 11 matched pairs of communities likely reduces the potential for confounding and despite the very large sample size (n = 13,268), the generalizability of this finding to U.S. smokers overall may be somewhat limited due to the use of a non-representative population (*i.e.*, those seeking assistance to quit smoking).

Multivariate regression models using data from the 2003 and 2006/07 TUS-CPS (Fagan et al., 2010) indicate that daily menthol smokers who report smoking ≤ 5 , 6–10, 11–19 or ≥ 20 cigarettes per day are statistically no more likely to smoke within 30 min of waking compared to non-menthol smokers. In addition, menthol smokers who report smoking ≤ 5 , 11–19 or ≥ 20 cigarettes per day are statistically no more likely to smoke within 5 min of waking; a statistically significant increase for smoking within 5 min of waking is reported only among those daily menthol smokers who report smoking 6-10 cigarettes per day. Mean time to first cigarette is not statistically different among daily menthol compared to non-menthol smokers overall, is statistically longer among non-Hispanic Whites, and is statistically shorter among non-Hispanic Blacks (Fagan et al., 2010). A separate analysis of the same data set (Lawrence et al., 2010), adjusted for demographic and smoking behavior variables, indicates that menthol cigarette use is not statistically associated with an increased odds of smoking within 30 min of waking, overall or when stratified by gender or race.

Thus, three studies (Fagan et al., 2010; Hyland et al., 2002; Lawrence et al., 2010) present adjusted analyses from either very large or nationally representative samples to indicate that menthol smokers, overall, do not report a statistically shorter time to first cigarette after waking compared to non-menthol smokers.

2. Materials and methods

The National Health and Nutrition Examination Survey (NHANES), National Survey on Drug Use and Health (NSDUH), NHIS and TUS-CPS provide nationally representative samples of smokers in sufficient numbers to examine number of cigarettes smoked per day among menthol and non-menthol cigarette smokers. In

addition, NHANES, NSDUH and TUS-CPS allow for examination of time to first cigarette after waking and HSI.

Detailed descriptions of the surveys, *i.e.*, NHANES (1999–2010), NSDUH (2000–2009), NHIS (2005 and 2010) and TUS-CPS (2003 and 2006/07), and methods used for the current analyses are provided elsewhere (Supplemental materials and methods). All calculations are weighted to the U.S. population, and use survey statistics to account for the complex sample designs to properly estimate variances. Moreover, analyses are constructed with the goal of maximizing comparability across data sets.

Differences between menthol and non-menthol cigarette smokers are considered statistically significant if tests indicate p < 0.05, or if 95% confidence intervals do not overlap in comparisons of distributions across multiple strata. When outcomes are measured on a continuous scale, means for menthol and non-menthol cigarette smokers are compared using linear regression models that adjust for socio-demographic covariates. When outcomes are measured categorically, logistic regression models are used to assess differences in odds of the outcome for menthol compared to non-menthol cigarette smokers, controlling for covariates. Thus, the current analyses account for known or suspected confounding of the association between menthol cigarette use and measures of dependence through stratification (descriptive analyses) and/or statistical adjustment (regression analyses) for gender, race/ethnicity and/or current age. Both linear and logistic regression analyses provide 95% confidence intervals.

Discussions of the results from these analyses include findings from unadjusted and fully adjusted analyses, while overall conclusions rely on findings from the fully adjusted regression models. In some instances, findings from unadjusted analyses are presented in detail for comparison to the existing literature. Detailed results of all analyses, including intermediate analyses (i.e., unadjusted descriptive analyses and partially adjusted regression models), are provided as supplemental materials (Supplemental Tables).

2.1. Definitions

Three different definitions are used to identify current smokers, based on smoking frequency (*i.e.*, number of days smoked during the past month), as follows: (1) past-month smokers, or individuals who smoked part or all of a cigarette on $\geqslant 1$ day during the month preceding participation in the survey; (2) regular smokers, or those who smoked on $\geqslant 10$ days during the month prior to the survey; and, (3) daily smokers, or those who smoked on all 30 days prior to the survey. All surveys except for the NSDUH and NHANES (youth only) limit smoking-related questions to those individuals who have smoked $\geqslant 100$ cigarettes lifetime (*i.e.*, lifetime smokers). Menthol cigarette smokers are defined on the basis of their usual or current type of cigarette used, depending on the wording of the survey question.

The use of menthol and non-menthol cigarettes by adult smokers is assessed in NHANES, NSDUH, NHIS and TUS-CPS using current age categories, as follows: ages 20–25, ages 26–29 and ages ≥30 years; use of menthol cigarettes by youth is assessed in NHANES using age categories, ages 12–15 and ages 16–19 years, and in the TUS-CPS for those ages 15–19 years (proxy data were excluded from analyses). Race/ethnicity is categorized as non-Hispanic White, non-Hispanic Black, and other races/ethnicities (combined).

For the current analyses, measures of dependence include reported number of cigarettes smoked per day as continuous or categorical data, depending on the survey question; time to first cigarette after waking (\leq 5, 6–30, 31–60 or >60 min); and, HSI (1–2 = low dependence; 3–4 = moderate dependence; or, 5–6 = high dependence), which integrates both cigarettes smoked per day and time to first cigarette (Heatherton et al., 1989).

Unadjusted analyses of HSI among menthol versus non-menthol cigarette smokers were conducted based on a three-category classification (as noted above), as well as the underlying six-point scale. Use of the six-point scale, in some instances, resulted in categories with small numbers of respondents; thus, the three-category classification was used for regression analyses.

3. Results

3.1. Cigarettes smoked per day

3.1.1. National Health and Nutrition Examination Survey (1999–2010)

Unadjusted analyses based on adult data from NHANES indicate that past-month smokers, regular smokers and daily smokers who use menthol cigarettes report smoking statistically fewer cigarettes per day compared to non-menthol smokers (~2.5–3.2 fewer cigarettes per day, overall) (Supplemental Tables 1A–1C); differences in mean numbers of cigarettes smoked per day are greater as smoking frequency (i.e., number of days smoked during the past month) increases. Within demographic strata, statistically fewer cigarettes per day are reported, regardless of smoking frequency, among menthol compared to non-menthol smokers who are male (~2.6–3.4 fewer), female (~2.0–2.4 fewer), non-Hispanic White (~1.8 fewer) and ages ≥30 years (~2.8–3.3 fewer); the greatest differences among menthol versus non-menthol smokers are for those who smoke daily.

Estimates from regression models that control for demographic variables (Table 1; Supplemental Tables R1A–R1C) indicate that daily smokers who use menthol cigarettes report smoking statistically fewer cigarettes per day compared to non-menthol smokers (16.67 versus 17.56 cigarettes per day, p = 0.01). Likewise, regular smokers who use menthol compared to non-menthol cigarettes smoke statistically fewer cigarettes per day (15.33 versus 16.06 cigarettes per day, p = 0.04), with no statistically significant difference among past-month smokers (14.56 versus 15.17 cigarettes per day, p = 0.08) when controlling for demographic variables. Differences in number of cigarettes smoked per day among menthol versus non-menthol smokers are small in magnitude.

Unadjusted analyses specific to youth indicate that past-month smokers, regular smokers and daily smokers who use menthol cigarettes report smoking fewer cigarettes per day (\sim 1.0–2.0 fewer cigarettes per day, overall) compared to non-menthol smokers (Supplemental Table 2); the difference among past-month smokers is statistically significant. Within demographic strata, statistically fewer cigarettes per day are reported among menthol versus non-menthol smokers who smoked on \geqslant 1 day during the past month and who are female (\sim 2.2 fewer), non-Hispanic White (\sim 2.1 fewer), other race/ethnicity (\sim 2.2 fewer) and ages 16–19 years (\sim 2.1 fewer).

Regression analyses that control for demographic variables (Table 2; Supplemental Tables R2A–R2C) indicate no statistically significant differences in cigarettes smoked per day among regular smokers or daily smokers who use menthol compared to non-menthol cigarettes. In contrast, the mean number of cigarettes smoked per day among past-month smokers who use menthol cigarettes is statistically lower compared to non-menthol smokers (4.81 versus 6.55 cigarettes per day, p = 0.001) when controlling for demographic variables.

3.1.2. National Survey on Drug Use and Health (2000–2009)

Unadjusted analyses of NSDUH data are conducted based on categories of cigarettes smoked per day (≤10, 11–20 and >20) among adult smokers. Overall, statistically higher percentages of past-month smokers, regular smokers and daily smokers who use menthol cigarettes report smoking ≤10 cigarettes per day

Table 1
Regression analyses of mean numbers of cigarettes smoked per day^a among adult menthol versus non-menthol smokers, adjusted for demographic variables (NHANES, 1999–2010)

Parameter	Past-month smok	ers ^d		Regular smokers ^e			Daily smokers ^f		
	Coefficient (SE ^b)	95% CI ^c	p-Value	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	p-Value
Intercept	14.56 (0.49)	13.57, 15.54	<0.0001	15.33 (0.50)	14.34, 16.31	<0.0001	16.67 (0.52)	15.64, 17.69	<0.0001
Cigarette type Menthol Non-menthol	-ref- 0.61 (0.35)	-0.08, 1.30	0.08	-ref- 0.73 (0.35)	0.04, 1.43	0.04	-ref- 0.89 (0.34)	0.22, 1.57	0.01
Gender Male Female	-ref- -2.21 (0.33)	-2.86, -1.56	<0.0001	-ref- -2.44 (0.34)	-3.12, -1.77	<0.0001	-ref- -2.77 (0.34)	-3.46, -2.09	<0.0001
Race/ethnicity Non-Hispanic White Non-Hispanic Black Other	-ref- -6.12 (0.43) -7.29 (0.46)	-6.98, -5.27 -8.21, -6.37	<0.0001	-ref- -6.37 (0.43) -6.92 (0.49)	-7.22, -5.52 -7.89, -5.95	<0.0001	-ref- -6.44 (0.45) -6.38 (0.54)	-7.34, -5.55 -7.46, -5.31	<0.0001
Current age (years) 20-25 26-29 ≥30	-ref- 0.03 (0.63) 4.40 (0.42)	-1.24, 1.29 3.57, 5.23	<0.0001	-ref- -0.18 (0.61) 4.24 (0.42)	-1.40, 1.04 3.40, 5.07	<0.0001	-ref- 0.06 (0.62) 4.02 (0.46)	-1.16, 1.29 3.11, 4.93	<0.0001

^a "During the past 30 days, on the days that [you] smoked, about how many cigarettes did [you] smoke per day?".

Table 2Regression analyses of mean numbers of cigarettes smoked per day^a among youth menthol versus non-menthol smokers, adjusted for demographic variables (NHANES, 1999–2010).

Parameter	Past-month smok	ers ^d		Regular smokerse			Daily smokers ^f		
	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	p-Value	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value
Intercept	4.81 (0.81)	3.21, 6.41	<0.0001	8.37 (1.31)	5.77, 10.97	<0.0001	11.46 (1.82)	7.85, 15.08	<0.0001
Cigarette type Menthol Non-menthol	-ref- 1.74 (0.50)	0.75, 2.73	0.001	-ref- 1.00 (0.71)	-0.41, 2.42	0.16	-ref- 1.01 (0.96)	-0.90, 2.93	0.30
Gender Male Female	-ref- -1.49 (0.48)	-2.45, -0.53	0.003	-ref- -2.39 (0.64)	-3.67, -1.11	0.0004	-ref- -3.53 (0.69)	-4.90, -2.16	<0.0001
Race/ethnicity Non-Hispanic White Non-Hispanic Black Other	-ref- -3.62 (0.63) -3.19 (0.60)	-4.87, -2.37 -4.40, -1.99	<0.0001	-ref- -4.11 (0.97) -3.53 (0.93)	-6.04, -2.18 -5.38, -1.67	<0.0001	-ref- -4.57 (1.47) -3.52 (1.23)	-7.49, -1.65 -5.97, -1.08	0.001
Current age (years) 12-15 16-19	-ref- 2.59 (0.67)	1.27, 3.91	0.0002	-ref- 2.10 (1.02)	0.06, 4.13	0.04	-ref- 2.21 (1.40)	-0.57, 4.99	0.12

^a 1999–2002: "During the past 30 days, on the days that you smoked, how many cigarettes did you smoke per day?" 2003–2010: "During the past 30 days, on the days that [you] smoked, about how many cigarettes did [you] smoke per day?".

compared to non-menthol smokers (Fig. 1, daily smokers only; Supplemental Tables 3A–3C); and, statistically lower percentages of menthol compared to non-menthol smokers report smoking 11–20 and >20 cigarettes per day. Within demographic strata, menthol smokers who are male, female, non-Hispanic White, ages 20–25 years, ages 26–29 years and ages \geqslant 30 years are statistically more likely than non-menthol smokers to smoke \leqslant 10 cigarettes per day, regardless of smoking frequency; there are no instances whereby a statistically higher percentage of non-menthol compared to menthol smokers report smoking \leqslant 10 cigarettes per day.

Differences are not observed, however, when controlling for demographic variables in regression analyses (Table 3; Supplemental Tables R3A–R3C); specifically, there are no statistically significant differences in the odds of being in the lowest smoking category (i.e., ≤ 10 cigarettes per day) among past-month smokers, regular smokers or daily smokers who use menthol compared to non-menthol cigarettes.

3.1.3. National Health Interview Survey (2005 and 2010)

Unadjusted analyses based on adult data from NHIS indicate that past-month smokers, regular smokers and daily smokers

^b Standard error of the regression coefficient.

^c 95% confidence interval.

 $^{^{\}rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.

 $^{^{\}rm e}$ Regular smokers defined as having smoked on \geqslant 10 days during the past month.

f Daily smokers defined as having smoked daily during the past month.

b Standard error of the regression coefficient.

c 95% confidence interval.

 $^{^{\}rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.

e Regular smokers defined as having smoked on ≥10 days during the past month.

^f Daily smokers defined as having smoked daily during the past month.

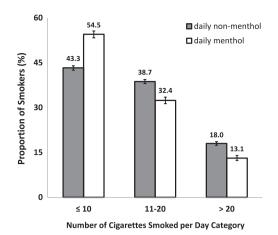


Fig. 1. Number of cigarettes smoked per day category distributions among adult daily menthol versus non-menthol smokers (NSDUH, 2000–2009). (Estimates are depicted as mean values with 95% confidence intervals.)

who use menthol cigarettes report smoking statistically fewer cigarettes per day compared to non-menthol smokers (\sim 2.5–2.8 fewer cigarettes per day, overall) (Supplemental Tables 4A–4C); differences in mean numbers of cigarettes smoked per day are greater as smoking frequency increases. Within demographic strata, statistically fewer cigarettes per day are reported, regardless of smoking frequency, among menthol compared to non-menthol smokers who are male (\sim 2.8–3.2 fewer), female (\sim 1.7–1.9 fewer), non-Hispanic White (\sim 1.3–1.5 fewer), non-Hispanic Black (\sim 1.1–1.6 fewer), other race/ethnicity (\sim 1.1–1.5 fewer), ages 20–25 years (\sim 0.8–1.3 fewer), ages 26–29 years (\sim 2.0–2.7 fewer) and ages \geqslant 30 years (\sim 2.5–2.8 fewer); the greatest differences among menthol versus non-menthol smokers are for those who smoke daily.

Estimates from regression models that control for demographic variables (Table 4; Supplemental Tables R4A–R4C) indicate that daily smokers who use menthol compared to non-menthol cigarettes report smoking statistically fewer cigarettes per day (15.02 versus 15.82 cigarettes per day, respectively; p = 0.001). Statisti-

cally fewer cigarettes per day are likewise reported among regular smokers and past-month smokers who use menthol compared to non-menthol cigarettes (13.34 versus 13.96 cigarettes per day, p = 0.01; and, 12.82 versus 13.36 cigarettes per day, p = 0.01; respectively) when controlling for demographic variables. Differences in number of cigarettes smoked per day among menthol versus non-menthol smokers are small in magnitude.

3.1.4. Tobacco Use Supplement – Current Population Survey (2003 and 2006/07)

Unadjusted analyses of TUS-CPS data are conducted based on categories of cigarettes smoked per day (\leq 10, 11–20, 21–30 and >30) among youth and adult smokers. Overall, statistically higher percentages of past-month smokers, regular smokers and daily smokers who use menthol cigarettes report smoking \leq 10 cigarettes per day compared to non-menthol smokers (Fig. 2, daily smokers only; Supplemental Tables 5A–5C); and, statistically lower percentages of menthol compared to non-menthol smokers report smoking 11–20, 21–30 and >30 cigarettes per day. Within demographic strata, menthol compared to non-menthol smokers are statistically more likely to report smoking \leq 10 cigarettes per day and statistically less likely to report smoking 11–20 and 21–30 cigarettes per day regardless of smoking frequency, with the only exceptions being among those who are ages 15–19 years and ages 20–25 years.

Estimates from regression models that control for demographic variables (Table 5; Supplemental Tables R5A–R5C) indicate that daily smokers who use menthol cigarettes report smoking statistically fewer cigarettes per day compared to non-menthol smokers (16.50 versus 16.88 cigarettes per day, p < 0.0001). Likewise, regular smokers and past-month smokers who use menthol compared to non-menthol cigarettes report smoking statistically fewer cigarettes per day (14.85 versus 15.26 cigarettes per day, p < 0.0001; and, 14.35 versus 14.68 cigarettes per day, p < 0.0001; respectively) when controlling for demographic variables. Differences in number of cigarettes smoked per day among menthol versus non-menthol smokers are small in magnitude.

Among youth, regression analyses that control for gender and race/ethnicity (Table 6; Supplemental Tables R5A-R5C) indicate

Table 3Regression analyses of cigarettes smoked per day^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (NSDUH, 2000–2009).

Parameter	Past-mor	nth smokers ^d		Regular s	smokers ^e		Daily sm	okers ^f	
	OR ^b	95% CI ^c	p-Value	ORb	95% CI [€]	p-Value	ORb	95% CI ^c	p-Value
Cigarettes per day ^a			0.82			0.42			0.32
≤ 10	-ref-			-ref-			-ref-		
11–20	0.99	0.93, 1.05		0.97	0.91, 1.04		0.96	0.89, 1.03	
>20	0.97	0.89, 1.06		0.94	0.86, 1.03		0.93	0.84, 1.03	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	1.59	1.52, 1.66		1.61	1.53, 1.70		1.64	1.55, 1.74	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	12.94	11.96, 14.00		13.38	12.15, 14.73		13.78	12.41, 15.30	
Other	1.58	1.47, 1.69		1.55	1.42, 1.68		1.51	1.37, 1.67	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20-25	-ref-			-ref-			-ref-		
26-29	0.82	0.77, 0.87		0.83	0.77, 0.89		0.79	0.73, 0.86	
≥30	0.80	0.77, 0.83		0.75	0.72, 0.78		0.71	0.68, 0.75	

a Smoked >1 day in last 30 days: "On the [# of days] you smoked cigarettes during the past 30 days, how many cigarettes did you smoke per day, on average?" Smoked 1 day in last 30 days: "On the one day you smoked cigarettes during the past 30 days, how many cigarettes did you smoke?".

^b Odds ratio, menthol versus non-menthol smokers.

c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥ 1 days during the past month.

Regular smokers defined as having smoked on ≥ 10 days during the past month.

Daily smokers defined as having smoked daily during the past month.

Table 4Regression analyses of mean numbers of cigarettes smoked per day^a among adult menthol versus non-menthol smokers, adjusted for demographic variables (NHIS, 2005 and 2010)

Parameter	Past-month smok	ers ^d		Regular smokers ^e			Daily smokers ^f		
	Coefficient (SE ^b)	95% CI ^c	p-Value	Coefficient (SE ^b)	95% CI ^c	p-Value	Coefficient (SE ^b)	95% CI ^c	p-Value
Intercept	12.82 (0.34)	12.15, 13.50	<0.0001	13.34 (0.35)	12.64, 14.0	<0.0001	15.02 (0.37)	14.30, 15.74	<0.0001
Cigarette type Menthol Non-menthol	-ref- 0.54 (0.22)	0.11, 0.97	0.01	-ref- 0.62 (0.23)	0.16, 1.07	0.01	-ref- 0.80 (0.24)	0.33, 1.26	0.001
Gender Male Female	-ref- -2.70 (0.20)	-3.10, -2.31	<0.0001	-ref- -2.87 (0.20)	-3.27, -2.5	<0.0001	-ref- -3.13 (0.22)	-3.56, -2.69	<0.0001
Race/ethnicity Non-Hispanic White Non-Hispanic Black Other	-ref- -4.77 (0.29) -6.57 (0.28)	-5.35, -4.20 -7.11, -6.03	<0.0001	-ref- -4.89 (0.30) -6.32 (0.29)	-5.48, -4.3 -6.90, -5.7	<0.0001	-ref- -5.07 (0.32) -6.48 (0.33)	-5.70, -4.45 -7.12, -5.84	<0.0001
Current age (years) 20-25 26-29 ≥30	-ref- 1.05 (0.41) 4.16 (0.30)	0.25, 1.85 3.56, 4.75	<0.0001	-ref- 1.43 (0.40) 4.18 (0.30)	0.63, 2.22 3.58, 4.78	<0.0001	-ref- 0.97 (0.40) 3.66 (0.31)	0.17, 1.77 3.04, 4.27	<0.0001

- ^a "On the average, when you smoked during the past 30 days, about how many cigarettes did you smoked a day?".
- ^b Standard error of the regression coefficient.
- ^c 95% confidence interval.
- $^{\rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.
- $^{\rm e}\,$ Regular smokers defined as having smoked on $\geqslant\!10$ days during the past month.
- ^f Daily smokers defined as having smoked daily during the past month.

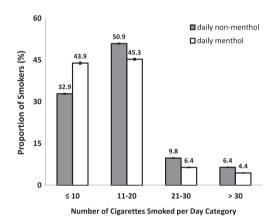


Fig. 2. Number of cigarettes smoked per day category distributions among adult and youth daily menthol versus non-menthol smokers (TUS-CPS, 2003 and 2006/07). (Estimates are depicted as mean values with 95% confidence intervals.)

no statistically significant differences in the number of cigarettes smoked per day among past-month smokers, regular smokers or daily smokers who use menthol compared to non-menthol cigarettes.

3.1.5. Summary of data on cigarettes smoked per day

These analyses provide estimates for numbers of cigarettes smoked per day among menthol compared to non-menthol smokers, based on nationally representative samples. Estimates from regression models that control for demographic variables consistently demonstrate that menthol smoking among adults (NHANES, NSDUH, NHIS and TUS-CPS) and among youth (NHANES and TUS-CPS) is not associated with smoking more cigarettes per day compared to non-menthol smoking (Table 7). To the contrary, adult menthol smokers (NHANES, NHIS and TUS-CPS) are more likely to smoke statistically fewer cigarettes per day compared to non-menthol smokers. Differences in number of cigarettes smoked per day among adult menthol compared to non-menthol smokers are generally small in magnitude, *i.e.*, <1 cigarettes per day

(NHANES and NHIS). In contrast, youth menthol smokers who report smoking on $\geqslant 1$ day during the past month indicate smoking ~ 2 fewer cigarettes per day (*i.e.*, $\sim 27\%$ fewer cigarettes per day) compared to non-menthol smokers (NHANES).

3.2. Time to first cigarette after waking

3.2.1. National Health and Nutrition Examination Survey (2001–2010)

Unadjusted analyses based on data from NHANES indicate that the distributions across categories of time to first cigarette after waking (\leq 5, 6–30, 31–60 and >60 min) among past-month smokers, regular smokers and daily smokers are not statistically different for adults who use menthol compared to non-menthol cigarettes (Fig. 3, daily smokers only; Supplemental Tables 6A-6C). Moreover, the proportions of menthol and non-menthol cigarette smokers who report smoking within the first 5 min of waking are not statistically different, regardless of smoking frequency (i.e., smoked ≥ 1 day, ≥ 10 days or daily during the past month). Within demographic strata, the distributions across categories of time to first cigarette among past-month smokers, regular smokers and daily smokers are not statistically different among menthol compared to non-menthol smokers. There are no instances whereby statistically higher proportions of menthol smokers report smoking a first cigarette within 5 min of waking, or statistically lower proportions report smoking 6-30, 31-60 or >60 min after waking compared to non-menthol smokers, regardless of smoking frequency.

Estimates from regression models that control for demographic variables (Table 8; Supplemental Tables R6A-R6C) indicate that the distributions across categories of time to first cigarette after waking among past-month smokers, regular smokers and daily smokers who use menthol compared to non-menthol cigarettes are not statistically different.

The distribution of youth smokers into categories of time to first cigarette after waking, overall and particularly when stratifying by demographic variables, results in small numbers of respondents in each category (Supplemental Tables 7A–7C); also, the numbers of menthol smokers represented in these categories decreases with

Table 5Regression analyses of mean numbers of cigarettes smoked per day^a among adult menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07).

Parameter	Past-month smok	ers ^d		Regular smokers ^e			Daily smokers ^f		
	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	p-Value
Intercept	14.35 (0.05)	14.24, 14.45	<0.0001	14.85 (0.06)	14.74, 14.96	<0.0001	16.50 (0.06)	16.38, 16.61	<0.0001
Cigarette type Menthol Non-menthol	-ref- 0.33 (0.04)	0.26, 0.41	<0.0001	-ref- 0.41 (0.04)	0.34, 0.49	<0.0001	-ref- 0.38 (0.04)	0.31, 0.46	<0.0001
Gender Male Female	-ref- -2.84 (0.03)	-2.90, -2.79	<0.0001	-ref- -2.98 (0.03)	-3.04, -2.92	<0.0001	-ref- -3.21 (0.03)	-3.27, -3.15	<0.0001
Race/ethnicity Non-Hispanic White Non-Hispanic Black Other	-ref- -5.01 (0.05) -6.01 (0.05)	-5.12, -4.91 -6.10, -5.91	<0.0001	-ref- -5.17 (0.05) -5.69 (0.05)	-5.28, -5.07 -5.79, -5.59	<0.0001	-ref- -5.19 (0.06) -5.47 (0.05)	-5.31, -5.08 -5.58, -5.36	<0.0001
Current age (years) 20-25 26-29 ≥30	-ref- 0.96 (0.07) 4.10 (0.05)	0.82, 1.10 4.01, 4.19	<0.0001	-ref- 1.11 (0.07) 4.09 (0.05)	0.96, 1.25 3.99, 4.18	<0.0001	-ref- 1.07 (0.08) 3.80 (0.05)	0.92, 1.22 3.70, 3.89	<0.0001

^a Some-day smokers: "On the average, of those [# days smoked] days, how many cigarettes did you usually smoke each day?" Daily smokers: "On the average, about how many cigarettes do you now smoke each day?".

Table 6Regression analyses of mean numbers of cigarettes smoked per day^a among youth menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07).

Parameter	Past-month smok	ers ^d		Regular smokers ^e			Daily smokers ^f		
	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value	Coefficient (SE ^b)	95% CI ^c	<i>p</i> -Value
Intercept	12.49 (0.18)	12.14, 12.85	<0.0001	12.92 (0.19)	12.56, 13.29	<0.0001	14.76 (0.19)	14.37, 15.15	<0.0001
Cigarette type Menthol Non-menthol	-ref- 0.29 (0.17)	-0.05, 0.63	0.10	-ref- 0.31 (0.18)	-0.05, 0.67	0.09	-ref- 0.03 (0.20)	-0.37, 0.43	0.89
Gender Male Female	-ref- -1.76 (0.16)	-2.07, -1.45	<0.0001	-ref- -2.00 (0.15)	-2.30, -1.70	<0.0001	-ref- -2.64 (0.16)	-2.96, -2.32	<0.0001
Race/ethnicity Non-Hispanic White Non-Hispanic Black Other	-ref- -2.87 (0.29) -2.60 (0.24)	-3.44, -2.30 -3.07, -2.14	<0.0001	-ref- -2.87 (0.29) -2.09 (0.24)	-3.44, -2.30 -2.56, -1.62	<0.0001	-ref- -4.11 (0.30) -1.29 (0.28)	-4.70, -3.52 -1.84, -0.74	<0.0001

^a Some-day smokers: "On the average, of those [# days smoked] days, how many cigarettes did you usually smoke each day?" Daily smokers: "On the average, about how many cigarettes do you now smoke each day?".

increased smoking frequency. Consequently, estimates are only provided for past-month smokers (i.e., smoked $\geqslant 1$ day during the past month), and a discussion of the findings is limited to the overall population of smokers and corresponding regression analyses.

Estimates from unadjusted analyses indicate that the proportions of youth past-month menthol cigarette smokers who report first smoking ≤5, 6–30, 31–60 and >60 min after waking are 13.22%, 12.25%, 12.98% and 61.54%, compared to 16.30%, 20.42%, 15.17% and 48.11%, respectively, for non-menthol smokers (Supplemental Table 7A). Thus, smaller proportions of menthol smokers report smoking a first cigarette ≤5 min, 6–30 min and 31–60 min after waking compared to non-menthol smokers, with the

only statistically significant difference being among those first smoking >60 min after waking (61.54% of menthol smokers versus 48.11% of non-menthol smokers). Regression analyses (Supplemental Tables R7A–R7C) indicate that menthol versus non-menthol (past-month) smokers have a higher odds of reporting a longer time to first cigarette after waking (e.g., >60 min; OR: 1.54, 95% CI: 0.94, 2.53; p = 0.04) when controlling for gender, race/ethnicity and current age.

3.2.2. National Survey on Drug Use and Health (2001–2009)

Unadjusted analyses based on adult data from NSDUH indicate few statistical differences in the distribution across categories of time to first cigarette (\leq 5, 6–30, 31–60 and >60 min) among

^b Standard error of the regression coefficient.

^c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥1 days during the past month.

 $^{^{\}rm e}$ Regular smokers defined as having smoked on \geqslant 10 days during the past month.

^f Daily smokers defined as having smoked daily during the past month.

^b Standard error of the regression coefficient.

^c 95% confidence interval.

 $^{^{\}rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.

 $^{^{\}rm e}\,$ Regular smokers defined as having smoked on $\geqslant\!10$ days during the past month.

f Daily smokers defined as having smoked daily during the past month.

Table 7
Summary of regression analyses examining number of cigarettes smoked per day, time to first cigarette after waking and Heaviness of Smoking Index among menthol versus non-menthol smokers

	NHANES		NSDUH	NHIS	TUS-CPS	
	Youtha	Adults ^b	Adults ^b	Adults ^b	Youth ^c	Adults ^d
Number of cigarettes smoked per day Time to first cigarette after waking Heaviness of Smoking Index	Fewer ^e Longer ^e No difference	Fewer ^{f,g} No difference No difference	No difference Shorter ^{e,f,g} Higher ^e	Fewer ^{e,f,g} - -	No difference Longer ^{f,g} No difference	Fewer ^{e,f,g} Longer ^e Lower ^{e,f,g}

^a Ages 12-19 years.

^g Daily smokers, defined as smoking all 30 days during the past month.

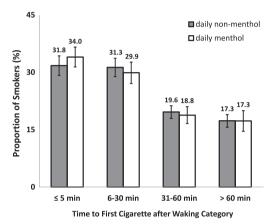


Fig. 3. Time to first cigarette category distributions among adult daily menthol

mean values with 95% confidence intervals.)

past-month smokers, regular smokers and daily smokers who use menthol compared to non-menthol cigarettes (Fig. 4, daily smokers only; Supplemental Tables 8A–8C). Statistically higher proportions

versus non-menthol smokers (NHANES, 2001-2010). (Estimates are depicted as

of menthol compared to non-menthol cigarette smokers report smoking within the first 5 min of waking (past-month smokers: 21.4% versus 19.0%; regular smokers: 22.7% versus 20.8%; daily smokers: 26.4% versus 24.1%), while statistically lower proportions of menthol smokers indicate first smoking 6–30 min after waking (regular smokers: 34.8% versus 36.9%; daily smokers: 39.2% versus 41.7%). Differences in the distribution across categories of time to first cigarette among menthol versus non-menthol smokers are small in magnitude (Fig. 4).

Within demographic strata based on gender and across smoking frequencies (*i.e.*, smoked ≥1 day, ≥10 days or daily during the past month), there are no consistent trends in the distribution of time to first cigarette after waking among menthol compared to non-menthol smokers; statistically significant differences are small in magnitude, and limited to a single response category. Differences among non-Hispanic White and non-Hispanic Black smokers who use menthol compared to non-menthol cigarettes are likewise inconsistent, and do not involve more than a single response category; however, statistically higher proportions of other race/ethnicity smokers who use menthol cigarettes report smoking within the first 5 min of waking, with corresponding lower proportions indicating first smoking >60 min after waking.

Table 8
Regression analyses of time to first cigarette^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (NHANES, 2001–2010).

Parameter	Past-mon	ith smokers ^d		Regular s	mokers ^e		Daily sm	okers ^f	
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value	OR ^b	95% CI [€]	p-Value
Time to first cigarette			0.83			0.85			0.79
≤5 min	-ref-			-ref-			-ref-		
6-30 min	0.98	0.81, 1.20		0.99	0.81, 1.20		0.99	0.81, 1.20	
31-60 min	0.93	0.73, 1.18		0.93	0.73, 1.18		0.90	0.71, 1.14	
>60 min	0.88	0.67, 1.16		0.89	0.68, 1.17		0.88	0.65, 1.20	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	2.08	1.79, 2.42		2.06	1.78, 2.39		2.11	1.80, 2.46	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	12.07	9.56, 15.23		12.09	9.54, 15.30		12.2	9.52, 15.63	
Other	1.02	0.78, 1.33		1.02	0.78, 1.33		1.03	0.78, 1.36	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20-25	-ref-			-ref-			-ref-		
26-29	0.95	0.65, 1.39		0.95	0.64, 1.39		0.94	0.64, 1.38	
≥30	0.58	0.44, 0.76		0.57	0.43, 0.75		0.56	0.42, 0.76	

a "How soon after [you] [wake] up [do you] smoke?" [question followed category options, *e.g.*, ≤5 min, 6–30 min, etc.]. Data for time to first cigarette were available beginning in 2001.

^b Ages 20 years and older.

c Ages 15-19 years.

d Ages 15 years and older.

^e Past-month smokers, defined as having smoked ≥1 days in the past month.

f Regular smokers, defined as having smoked ≥ 10 days in the past month.

^b Odds ratio, menthol versus non-menthol smokers.

^c 95% confidence interval.

 $^{^{\}rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.

 $^{^{\}rm e}\,$ Regular smokers defined as having smoked on $\geqslant\!10$ days during the past month.

f Daily smokers defined as having smoked daily during the past month.

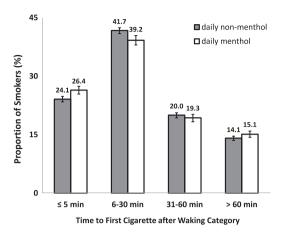


Fig. 4. Time to first cigarette category distributions among adult daily menthol versus non-menthol smokers (NSDUH, 2001–2009). (Estimates are depicted as mean values with 95% confidence intervals.)

Statistically higher proportions of menthol compared to non-menthol cigarette smokers who are ages 26–29 years report smoking within the first 5 min of waking, with corresponding lower proportions indicating first smoking either 31–60 or >60 min after waking; similar differences are reported among past-month smokers and regular smokers who are ages 20–25 years, but not among daily smokers. Among menthol compared to non-menthol smokers who are ages ≥30 years, statistically significant differences in the distribution across categories of time to first cigarette after waking are either small in magnitude or limited to a single response category.

Estimates from regression models that control for demographic variables (Table 9; Supplemental Tables R8A–R8C) indicate that the distribution across categories of time to first cigarette after waking among daily menthol smokers trend statistically shorter compared to non-menthol smokers (e.g., >60 min after waking; OR: 0.84, 95% CI: 0.75, 0.94; p = 0.002). Category distributions likewise trend toward a shorter time to first cigarette among regular smokers and past-month smokers who use menthol compared to

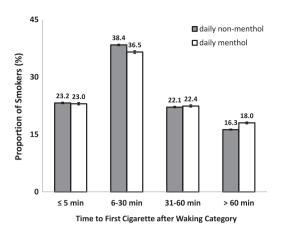


Fig. 5. Time to first cigarette category distributions among adult and youth daily menthol versus non-menthol smokers (TUS-CPS, 2003 and 2006/07). (Estimates are depicted as mean values with 95% confidence intervals.)

non-menthol cigarettes (e.g., >60 min after waking; OR: 0.83, 95% CI: 0.76, 0.90; p < 0.0001; OR: 0.79, 95% CI: 0.73, 0.85; p = 0.04; respectively) when controlling for demographic variables.

3.2.3. Tobacco Use Supplement – Current Population Survey (2003 and 2006/07)

Unadjusted analyses based on adult and youth data from TUS-CPS indicate that there are few statistical differences in the distribution across categories of time to first cigarette after waking (≤5, 6–30, 31–60 and >60 min) among past-month smokers, regular smokers and daily smokers who use menthol compared to nonmenthol cigarettes (Fig. 5, daily smokers only; Supplemental Tables 9A–9C). Statistically lower proportions of menthol compared to non-menthol cigarette smokers report smoking within 6–30 min of waking (past-month smokers: 32.2% versus 33.7%; regular smokers: 33.2% versus 35.0%; daily smokers: 36.5% versus 38.4%), while statistically higher proportions indicate first smoking >60 min after waking (past-month smokers: 26.9% versus 25.6%; regular smokers: 24.5% versus 22.8%; daily smokers: 18.0% versus

Table 9Regression analyses of time to first cigarette^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (NSDUH, 2001–2009).

Parameter	Past-mor	nth smokers ^d		Regular s	smokers ^e		Daily smokers ^f		
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	<i>p</i> -Value
Time to first cigarette			0.04			<0.0001			0.002
≤5 min	-ref-			-ref-			-ref-		
6-30 min	0.87	0.81, 0.93		0.86	0.80, 0.93		0.87	0.81, 0.94	
31-60 min	0.87	0.80, 0.95		0.86	0.79, 0.94		0.88	0.79, 0.97	
>60 min	0.79	0.73, 0.85		0.83	0.76, 0.90		0.84	0.75, 0.94	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	1.59	1.52, 1.67		1.61	1.53, 1.70		1.64	1.54, 1.74	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	13.75	12.64, 14.95		14.34	12.90, 15.93		15.1	13.61, 16.74	
Other	1.65	1.53, 1.79		1.63	1.49, 1.79		1.60	1.44, 1.78	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20–25	-ref-			-ref-			-ref-		
26-29	0.80	0.75, 0.86		0.81	0.75, 0.87		0.78	0.71, 0.86	
≥30	0.74	0.71, 0.77		0.70	0.67, 0.74		0.67	0.63, 0.71	

a Smoked daily in last 30 days: "How soon after you wake up do you have your first cigarette?" Smoked 1–29 days in last 30 days: "On the days that you smoke, how soon after you wake up do you have your first cigarette?" Data for time to first cigarette were available beginning in 2001.

^b Odds ratio, menthol versus non-menthol smokers.

c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥ 1 days during the past month.

Regular smokers defined as having smoked on ≥ 10 days during the past month.

Daily smokers defined as having smoked daily during the past month.

Table 10Regression analyses of time to first cigarette^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07)

Parameter	Past-moi	nth smokers ^d		Regular s	smokers ^e		Daily smokers ^f		
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value
Time to first cigarette			0.001			0.25			0.53
≤5 min	-ref-			-ref-			-ref-		
6-30 min	1.02	1.00, 1.05		1.02	1.00, 1.05		1.01	0.99, 1.04	
31-60 min	1.01	0.98, 1.04		1.01	0.98, 1.04		1.00	0.97, 1.03	
>60 min	0.97	0.95, 1.00		1.00	0.97, 1.03		1.01	0.99, 1.05	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	1.72	1.69, 1.74		1.70	1.67, 1.73		1.72	1.69, 1.75	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	11.81	11.43, 12.21		11.64	11.26, 12.03		11.74	11.35, 12.14	
Other	1.52	1.48, 1.56		1.52	1.48, 1.56		1.54	1.49, 1.58	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20–25	-ref-			-ref-			-ref-		
26-29	0.82	0.79, 0.85		0.83	0.80, 0.86		0.83	0.79, 0.86	
≥30	0.77	0.75, 0.80		0.77	0.75, 0.79		0.74	0.72, 0.77	

^a Some-day smokers: "On the days that you smoke, how soon after you wake up do you typically smoke your first cigarette of the day?" Daily smokers: "How soon after you wake up do you typically smoke your first cigarette of the day?".

Table 11Regression analyses of time to first cigarette^a category distributions among youth menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07).

Parameter	Past-mor	nth smokers ^d		Regular s	smokers ^e		Daily sm	okers ^f	
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	<i>p</i> -Value	OR ^b	95% CI [€]	p-Value
Time to first cigarette			0.06			0.01			<0.0001
≤5 min	-ref-			-ref-			-ref-		
6-30 min	1.03	0.94, 1.18		1.01	0.86, 1.15		1.01	0.88, 1.16	
31-60 min	1.15	1.00, 1.32		1.20	1.04, 1.38		1.28	1.11, 1.48	
>60 min	0.97	0.85, 1.11		0.96	0.83, 1.10		0.92	0.79, 1.07	
Gender			0.62			0.47			0.003
Male	-ref-			-ref-			-ref-		
Female	1.02	0.94, 1.11		1.03	0.95, 1.13		1.17	1.06, 1.29	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	5.82	4.73, 7.15		5.77	4.68, 7.13		6.52	5.03, 8.47	
Other	1.51	1.34, 1.70		1.42	1.25, 1.60		1.52	1.31, 1.75	

^a Some-day smokers: "On the days that you smoke, how soon after you wake up do you typically smoke your first cigarette of the day?" Daily smokers: "How soon after you wake up do you typically smoke your first cigarette of the day?".

16.3%). Differences in the distribution across categories of time to first cigarette among menthol versus non-menthol smokers are small in magnitude (Fig. 5).

Within demographic strata based on gender and across smoking frequencies (*i.e.*, smoked $\geqslant 1$ day, $\geqslant 10$ days or daily during the past month), statistically lower and statistically higher proportions of menthol compared to non-menthol smokers report smoking a first cigarette within 6–30 min and >60 min after waking, respectively; differences in time to first cigarette among menthol versus non-menthol smokers are small in magnitude. Estimates among non-Hispanic White and non-Hispanic Black smokers are consistent in suggesting that statistically lower and statistically higher proportions of menthol cigarette smokers report smoking within

the first 5 min of waking, respectively, with corresponding differences in longer responses categories; differences in time to first cigarette among menthol versus non-menthol smokers are small in magnitude. No consistent differences are reported among other race/ethnicity smokers who use menthol compared to non-menthol cigarettes. With regard to current age category, statistically higher proportions of menthol compared to non-menthol cigarette smokers who are ages 20–25 years report smoking within the first 5 min of waking, with corresponding lower proportions indicating first smoking >60 min after waking. However, statistically lower proportions of menthol cigarette smokers who are ages ≥30 years report smoking within the first 5 min and 6–30 min after waking, with corresponding higher proportions indicating first smoking

^b Odds ratio, menthol versus non-menthol smokers.

c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥1 days during the past month.

^e Regular smokers defined as having smoked on \ge 10 days during the past month.

^f Daily smokers defined as having smoked daily during the past month.

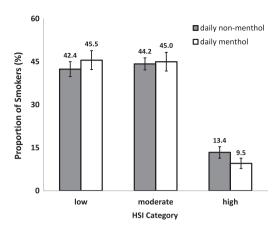
^b Odds ratio, menthol versus non-menthol smokers.

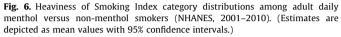
^c 95% confidence interval.

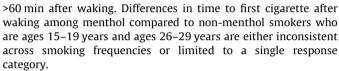
 $^{^{\}rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.

 $^{^{\}rm e}$ Regular smokers defined as having smoked on \geqslant 10 days during the past month.

f Daily smokers defined as having smoked daily during the past month.







Regression analyses that control for demographic variables (Table 10; Supplemental Tables R9A–R9C) indicate that category distributions for time to first cigarette after waking among adult daily menthol smokers are not statistically different compared to non-menthol smokers. Category distributions are not statistically different among regular smokers who use menthol compared to non-menthol cigarettes, but trend toward a statistically longer time to first cigarette among menthol smokers who report smoking on \geqslant 1 day during the past month (e.g., 6–30 min after waking; OR: 1.02, 95% CI: 1.00, 1.05; p = 0.001) when controlling for demographic variables. Specific to youth, estimates from regression models that control for gender and race/ethnicity (Table 11; Supplemental Tables R9A–R9C) indicate that daily smokers and regular smokers who use menthol cigarettes are more likely to have

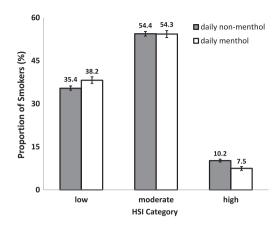


Fig. 7. Heaviness of Smoking Index category distributions among adult daily menthol versus non-menthol smokers (NSDUH, 2001–2009). (Estimates are depicted as mean values with 95% confidence intervals.)

their first cigarette 31–60 min after waking than non-menthol smokers (OR: 1.28, 95% CI: 1.11, 1.48, p < 0.0001; and, OR: 1.20, 95% CI: 1.04, 1.38, p = 0.01; respectively). Menthol smokers who report smoking on $\geqslant 1$ day during the past month have a slightly higher odds of being in a longer time to first cigarette category compared to non-menthol smokers (e.g., 31–60 min; OR: 1.15, 95% CI: 1.00, 1.32; p = 0.06) when controlling for gender and race/ethnicity.

3.2.4. Summary of data on time to first cigarette

These analyses provide estimates for category distributions of time to first cigarette after waking among menthol compared to non-menthol smokers, based on nationally representative samples (NHANES, NSDUH and TUS-CPS). Estimates from regression models that control for demographic variables appear to provide inconsistent findings among adult menthol compared to non-menthol cigarette smokers, but consistent findings among youth smokers (Table 7). However, a closer examination of the estimates provided by the three surveys demonstrates that, regardless of whether sta-

Table 12Regression analyses of Heaviness of Smoking Index^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (NHANES, 2001–2010).

Parameter	Past-mor	nth smokers ^d		Regular :	smokers ^e		Daily sm	okers ^f	
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value
Heaviness of Smoking Index			0.78			0.83			0.70
Low	-ref-			-ref-			-ref-		
Moderate	1.06	0.89, 1.26		1.05	0.88, 1.25		1.08	0.90, 1.30	
High	0.99	0.76, 1.28		0.99	0.76, 1.29		1.03	0.78, 1.35	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	2.08	1.79, 2.41		2.06	1.77, 2.39		2.11	1.80, 2.46	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	12.03	9.54, 15.18		12.05	9.52, 15.26		12.22	9.54, 15.66	
Other	1.00	0.78, 1.29		1.00	0.78, 1.29		1.02	0.79, 1.33	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20–25	-ref-			-ref-			-ref-		
26-29	0.95	0.64, 1.39		0.94	0.64, 1.39		0.94	0.64, 1.38	
≥30	0.58	0.44, 0.77		0.58	0.44, 0.76		0.57	0.42, 0.76	

a Data for time to first cigarette were available beginning in 2001; Heaviness of Smoking Index (HSI) categories: low = 1-2; moderate = 3-4; high = 5-6 (refer to Supplemental materials and methods).

^b Odds ratio, menthol versus non-menthol smokers.

c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥ 1 days during the past month.

Regular smokers defined as having smoked on ≥ 10 days during the past month.

Daily smokers defined as having smoked daily during the past month.

Table 13

Regression analyses of Heaviness of Smoking Index^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (NSDUH, 2001–2009)

Parameter	Past-month smokers ^d			Regular smokers ^e			Daily smokers ^f		
	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value
Heaviness of Smoking Index			0.003			0.08			0.53
Low	-ref-			-ref-			-ref-		
Moderate	1.1	1.04, 1.17		1.07	1.01, 1.14		1.04	0.97, 1.13	
High	1.06	0.95, 1.17		1.02	0.92, 1.15		1.02	0.90, 1.15	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	1.59	1.52, 1.67		1.61	1.53, 1.70		1.64	1.54, 1.74	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	13.82	12.72, 15.01		14.39	12.97, 15.96		15.17	13.69, 16.81	
Other	1.63	1.51, 1.76		1.62	1.48, 1.77		1.58	1.42, 1.75	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20–25	-ref-			-ref-			-ref-		
26-29	0.80	0.75, 0.86		0.81	0.75, 0.87		0.78	0.71, 0.85	
≥30	0.75	0.71, 0.78		0.71	0.67, 0.74		0.67	0.64, 0.71	

^a Data for time to first cigarette were available beginning in 2001; Heaviness of Smoking Index (HSI) categories: low = 1–2; moderate = 3–4; high = 5–6 (refer to Supplemental materials and methods).

^f Daily smokers defined as having smoked daily during the past month.

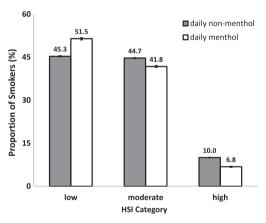


Fig. 8. Heaviness of Smoking Index category distributions among adult and youth daily menthol versus non-menthol smokers (TUS-CPS, 2003 and 2006/07). (Estimates are depicted as mean values with 95% confidence intervals.)

tistical differences are indicated, category distributions among adult menthol compared to non-menthol cigarette smokers are quite similar within each survey. Differences in the proportions of menthol and non-menthol smokers who report smoking a first cigarette ≤ 5 , 6–30, 31–60 or >60 min after waking are generally in the range of 2–3 percentage points, and are often limited to a single response category. As such, these data do not constitute evidence of either decreased or increased dependence among menthol compared to non-menthol smokers, based on time to first cigarette after waking.

Greater consistency in time to first cigarette after waking is indicated among youth smokers, whereby those who use menthol compared to non-menthol cigarettes generally have a higher odds of reporting a longer time to first cigarette after waking (NHANES, analyses limited to past-month smokers; TUS-CPS). However, differences in the proportions of menthol compared to non-menthol smokers indicating longer times to first cigarette are small in magnitude.

3.3. Heaviness of Smoking Index (HSI)

3.3.1. National Health and Nutrition Examination Survey (2001–2010)

Unadjusted analyses based on data from NHANES provide HSI category distributions (low = 1–2, moderate = 3–4 and high = 5–6) among past-month smokers, regular smokers and daily smokers that indicate a lower dependence among adults who use menthol compared to non-menthol cigarettes (Fig. 6, daily smokers only; Supplemental Tables 10A–10C). Specifically, the proportions of menthol cigarette smokers whose dependence is categorized as high are statistically lower compared to non-menthol smokers, with no statistically significant differences indicated for the low/moderate dependence categories.

Within demographic strata and across smoking frequencies (*i.e.*, smoked $\geqslant 1$ day, $\geqslant 10$ days or daily during the past month), statistically lower proportions of males and those ages $\geqslant 30$ years who use menthol compared to non-menthol cigarettes are distributed in the high dependence category; no other statistically significant differences are indicated.

Regression models that control for demographic variables (Table 12; Supplemental Tables R10A–R10C) indicate no statistically significant differences in HSI category distributions among past-month smokers, regular smokers and daily smokers who use menthol compared to non-menthol cigarettes.

The distribution of youth smokers into categories of HSI score, overall and when stratifying by demographic variables, results in small numbers of respondents in each of the three categories (Supplemental Tables 11A-11C); also, the numbers of menthol smokers represented in these categories decrease with increased smoking frequency. Consequently, estimates are only provided for pastmonth smokers (*i.e.*, smoked ≥ 1 day in the past 30 days), and a discussion of the findings is limited to the overall population of smokers and corresponding regression analyses.

Unadjusted analyses indicate that the proportions of youth past-month menthol cigarette smokers categorized as low, moderate and high in terms of dependence are 80.81%, 18.13% and 1.05%, compared to 75.43%, 22.86% and 1.79% for non-menthol smokers (Supplemental Table 11A); none of these differences is statistically

b Odds ratio, menthol versus non-menthol smokers.

^c 95% confidence interval.

^d Past-month smokers defined as having smoked on ≥ 1 days during the past month.

^e Regular smokers defined as having smoked on ≥ 10 days during the past month.

Table 14Regression analyses of Heaviness of Smoking Index^a category distributions among adult menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07).

Parameter	Past-month smokers ^d			Regular smokers ^e			Daily smokers ^f		
	ORb	95% CI [€]	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	p-Value
Heaviness of Smoking Index			<0.0001			<0.0001			<0.0001
Low	-ref-			-ref-			-ref-		
Moderate	0.99	0.97, 1.00		0.97	0.95, 0.99		0.97	0.95, 0.99	
High	0.91	0.88, 0.93		0.89	0.86, 0.92		0.90	0.87, 0.93	
Gender			< 0.0001			< 0.0001			< 0.0001
Male	-ref-			-ref-			-ref-		
Female	1.71	1.68, 1.73		1.69	1.66, 1.72		1.71	1.68, 1.74	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	11.70	11.32, 12.09		11.51	11.13, 11.89		11.61	11.23, 12.01	
Other	1.50	1.46, 1.54		1.50	1.46, 1.54		1.52	1.48, 1.57	
Current age (years)			< 0.0001			< 0.0001			< 0.0001
20-25	-ref-			-ref-			-ref-		
26-29	0.82	0.79, 0.85		0.83	0.80, 0.86		0.82	0.79, 0.86	
≥30	0.78	0.76, 0.81		0.78	0.76, 0.80		0.75	0.73, 0.77	

- ^a Heaviness of Smoking Index (HSI) categories: low = 1-2; moderate = 3-4; high = 5-6 (refer to Supplemental materials and methods).
- ^b Odds ratio, menthol versus non-menthol smokers.
- c 95% confidence interval.
- ^d Past-month smokers defined as having smoked on ≥ 1 days during the past month.
- ^e Regular smokers defined as having smoked on ≥10 days during the past month.
- f Daily smokers defined as having smoked daily during the past month.

significant. Corresponding regression analyses that control for gender, race/ethnicity and current age (Supplemental Tables R11A–R11C) indicate no statistically significant difference among menthol compared to non-menthol (past-month) cigarette smokers based on this composite measure of dependence.

3.3.2. National Survey on Drug Use and Health (2001–2009)

Unadjusted analyses based on NSDUH data provide HSI category distributions (low = 1–2, moderate = 3–4 and high = 5–6) among past-month smokers, regular smokers and daily smokers to suggest a lower level of dependence among adults who use menthol compared to non-menthol cigarettes (Fig. 7, daily smokers only; Supplemental Tables 12A–12C). Statistically higher proportions of regular smokers and daily smokers who use menthol compared to non-menthol cigarettes are in the low dependence category, while statistically lower proportions of past-month smokers, regular smokers and daily smokers who use menthol cigarettes are in the high dependence category. Differences in the distribution across categories of HSI among menthol versus non-menthol cigarettes smokers are small in magnitude.

Within demographic strata, numerically higher proportions of male menthol cigarette smokers indicate low dependence and statistically lower proportions of female menthol smokers indicate high dependence compared to non-menthol smokers. No consistent differences are indicated among non-Hispanic White and non-Hispanic Black smokers who use menthol compared to nonmenthol cigarettes, while statistically lower and statistically higher proportions of other race/ethnicity menthol smokers are in the low and moderate dependence categories, respectively. With regard to current age category, statistically higher and statistically lower proportions of menthol compared to non-menthol cigarette smokers who are ages ≥30 years indicate low and high dependence, respectively, with the differences in the distribution across categories of HSI among menthol versus non-menthol cigarette smokers being small in magnitude. No consistent differences in HSI are suggested among menthol smokers who are ages 20-25 years and ages 26–29 years compared to non-menthol smokers.

Regression models that control for demographic variables (Table 13; Supplemental Tables R12A–R12C) indicate no statistically significant differences in HSI category distributions among daily smokers and regular smokers who use menthol compared to non-menthol cigarettes. In contrast, a statistically higher odds of being in a higher HSI category is suggested among past-month smokers who use menthol compared to non-menthol cigarettes (e.g., moderate HSI; OR: 1.1, 95% CI: 1.04, 1.17; p = 0.003) when controlling for demographic variables.

3.3.3. Tobacco Use Supplement – Current Population Survey (2003 and 2006/07)

Unadjusted analyses based on TUS-CPS data provide HSI category distributions (low = 1–2, moderate = 3–4 and high = 5–6) among past-month smokers, regular smokers and daily smokers that indicate a lower dependence among adults and youth who use menthol compared to non-menthol cigarettes (Fig. 8, daily smokers only; Supplemental Tables 13A–13C). Menthol cigarette smokers are statistically more likely to be in low dependence categories, and statistically less likely to be in moderate or high dependence categories compared to non-menthol smokers.

Within demographic strata, statistically higher and statistically lower proportions of menthol cigarette smokers who are male, female and non-Hispanic White are in the low and moderate/high dependence categories, respectively, compared to non-menthol smokers; no consistent differences are indicated among non-Hispanic Black and other race/ethnicity smokers who use menthol compared to non-menthol cigarettes. Based on current age category, statistically higher and statistically lower proportions of menthol compared to non-menthol cigarette smokers who are ages ≥30 years indicate low and moderate/high dependence, respectively. Similar trends are indicated for menthol cigarette smokers who are ages 26–29 years (i.e., regular smokers and daily smokers), while no consistent differences are suggested among menthol compared to non-menthol smokers who are ages 15–19 years and ages 20–25 years.

Regression models that control for demographic variables (Table 14; Supplemental Tables R13A–R13C) indicate a statistically

Table 15Regression analyses of Heaviness of Smoking Index^a category distributions among youth menthol versus non-menthol smokers, adjusted for demographic variables (TUS-CPS, 2003 and 2006/07).

Parameter	Past-month smokers ^d			Regular smokers ^e			Daily smokers ^f		
	ORb	95% CI [€]	p-Value	ORb	95% CI ^c	p-Value	ORb	95% CI ^c	<i>p</i> -Value
Heaviness of Smoking Index			0.23			0.25			0.37
Low	-ref-			-ref-			-ref-		
Moderate	0.99	0.89, 1.10		0.99	0.89, 1.09		1.02	0.92, 1.14	
High	0.81	0.63, 1.03		0.81	0.63, 1.04		0.85	0.67, 1.09	
Gender			0.87			0.68			0.01
Male	-ref-			-ref-			-ref-		
Female	1.01	0.93, 1.10		1.02	0.93, 1.11		1.15	1.04, 1.27	
Race/ethnicity			< 0.0001			< 0.0001			< 0.0001
Non-Hispanic White	-ref-			-ref-			-ref-		
Non-Hispanic Black	5.70	4.64, 6.99		5.63	4.57, 6.95		6.29	4.84, 8.19	
Other	1.46	1.30, 1.64		1.36	1.20, 1.54		1.46	1.26, 1.69	

- ^a Heaviness of Smoking Index (HSI) categories: low = 1-2; moderate = 3-4; high = 5-6 (refer to Supplemental materials and methods).
- ^b Odds ratio, menthol versus non-menthol smokers.
- c 95% confidence interval.
- $^{\rm d}$ Past-month smokers defined as having smoked on $\geqslant 1$ days during the past month.
- $^{\rm e}$ Regular smokers defined as having smoked on \geqslant 10 days during the past month.
- f Daily smokers defined as having smoked daily during the past month.

higher odds of being in a lower HSI category among daily smokers who use menthol compared to non-menthol cigarettes (e.g., high HSI; OR: 0.90, 95% CI: 0.87, 0.93; p < 0.0001). Statistically lower dependence, based on HSI category distribution, is likewise indicated among regular smokers and past-month smokers who use menthol compared to non-menthol cigarettes (e.g., high HSI; OR: 0.89, 95% CI: 0.86, 0.92, p < 0.001; and, OR: 0.91, 95% CI: 0.88, 0.93, p < 0.001, respectively) when controlling for demographic variables. Specific to youth, regression analyses that control for gender and race/ethnicity (Table 15; Supplemental Tables R13A–R13C) indicate no statistically significant differences in HSI category distributions among past-month smokers, regular smokers and daily smokers who use menthol compared to non-menthol cigarettes.

3.3.4. Summary of data on Heaviness of Smoking Index

Three nationally representative surveys provide data on number of cigarettes smoked per day and time to first cigarette after waking, which in turn are used to calculate HSI category distributions among menthol compared to non-menthol smokers. Estimates from regression models that control for demographic variables provide generally consistent evidence to indicate that menthol compared to non-menthol cigarette use is not associated with being in a higher HSI category among adult or youth smokers (Table 7). Based on HSI category distributions, adult menthol cigarette smokers are either no more dependent (NHANES), or possibly less dependent than non-menthol smokers (TUS-CPS; includes smokers ages 15-19 years). While data from one of the surveys (NSDUH) suggests an increased dependence among past-month menthol compared to non-menthol cigarette smokers, no corresponding differences are indicated among regular smokers and daily smokers. Among youth smokers, estimates from regression models that control for demographic variables indicate no differences in the distribution of menthol compared to non-menthol cigarette smokers into HSI categories.

4. Conclusions

Results from the current analyses are consistent with findings from the limited number of published studies that include nationally representative samples and that appropriately control for covariates in evaluating the association between menthol cigarette use and dependence. Specifically, the available evidence demonstrates that menthol in cigarettes does not increase dependence

among U.S. smokers. The current analyses further examine primary measures of dependence (*i.e.*, number of cigarettes smoked per day and time to first cigarette after waking, which in turn are used to calculate Heaviness of Smoking Index) based on the available data from four nationally representative populations and utilizing three different definitions for current smokers (*i.e.*, smoked on $\geqslant 1$ day, smoked on $\geqslant 10$ days and smoked daily during the past month), and thus provide additional data to support an evidence-based determination on whether menthol in cigarettes affects dependence.

Regression analyses based on data from three of four surveys (NHANES, NHIS and TUS-CPS) indicate that adult menthol smokers do not report smoking more cigarettes per day compared to nonmenthol smokers. These findings are consistent with those from previously published studies examining adult data from U.S. government surveys (Fagan et al., 2010; Lawrence et al., 2010; Stahre et al., 2010). Data from the last of the surveys examined as part of the current analyses (NSDUH) indicate no differences in the number of cigarettes smoked per day, and thus no greater dependence among adult menthol compared to non-menthol smokers. These analyses likewise examine dependence among youth menthol compared to non-menthol cigarette smokers; neither of the two surveys examined (NHANES and TUS-CPS) provide data to indicate that menthol in cigarettes increases dependence.

With regard to time to first cigarette after waking among adult menthol compared to non-menthol cigarette smokers, the current regression analyses provide what could be interpreted as inconsistent findings. However, close examination of the estimates provided by NHANES, NSDUH and TUS-CPS shows that, regardless of whether statistically significant differences are indicated, category distributions for menthol and non-menthol cigarette smokers are nearly identical. Specifically, differences in the proportions of menthol and non-menthol smokers who report smoking a first cigarette ≤5, 6-30, 31-60 or >60 min after waking are generally in the range of 2–3 percentage points, and are often limited to a single response category. As such, these data do not constitute sufficient evidence of a difference in time to first cigarette after waking among menthol versus non-menthol smokers. The available evidence likewise indicates that youth menthol smokers have small but statistically higher odds of reporting a longer time to first cigarette after waking compared to non-menthol smokers (NHANES

Findings from current analyses on time to first cigarette after waking are generally consistent with results reported in a limited

number of published studies that examine this dependence measure among adult menthol compared to non-menthol smokers, based on other analyses of data from U.S. government surveys (Fagan et al., 2010; Lawrence et al., 2010; Stahre et al., 2010). In the only study that adjusted for covariates, Fagan et al. (2010) reported that menthol smokers are no more likely to smoke within 30 min of waking compared to non-menthol smokers, regardless of the number of cigarettes smoked per day. In addition, menthol smokers who report smoking $\leqslant 5$, 11-19 or $\geqslant 20$ cigarettes per day are no more likely to smoke within 5 min of waking compared to non-menthol smokers, while those who report smoking 6–10 cigarettes per day are more likely to smoke within 5 min of waking.

The Heaviness of Smoking Index is a composite measure of dependence that integrates number of cigarettes smoked per day and time to first cigarette after waking. The current analyses generally provide consistent evidence to indicate that menthol compared to non-menthol cigarette smoking is not associated with increased dependence among adult or youth smokers. Findings from regression models indicate that neither adult nor youth menthol cigarette smokers are statistically more likely to be in higher versus lower dependence categories compared to non-menthol smokers. And while findings from one survey (NSDUH) suggest that past-month menthol cigarette smokers are more likely to be in a higher versus lower dependence category than non-menthol smokers, no corresponding differences are indicated among regular smokers or daily smokers. Moreover, findings from a second survey (TUS-CPS) indicate that past-month smokers, regular smokers and daily smokers who use menthol compared to non-menthol cigarettes are statistically more likely to be in a lower versus higher dependence category. These findings are consistent with the limited number of published studies that present evidence on another composite measure of dependence (i.e., FTND), and that suggest no increase in dependence among menthol compared to non-menthol cigarette smokers (Okuyemi et al., 2004; Collins and Moolchan, 2006: Muscat et al., 2009: Brody et al., 2013: Reitzel et al., 2013). In contrast to the current analyses, none of the cited studies examined nationally representative populations of smokers, and none of the analyses attempted to control for covariates.

The purpose of this paper is to examine the potential association between menthol in cigarettes and dependence using several widely accepted measures; the purpose is not to evaluate the reliability and/or validity of those measures. With regard to limitations of the current analyses, the covariates selected for inclusion in regression analyses have been the subject of discussion in the literature and in regulatory context; analyses did not assess or control for all conceivable covariates, e.g., indicators of individual and neighborhood socioeconomic status. Likewise, analyses are based on commonly used measures of dependence, all of which have been suggested to correlate, to varying degrees, with biomarkers of exposure; there are no direct measures of physiological dependence on nicotine available for analysis in these data sets. These analyses are likewise subject to other limitations imposed by the data sources, i.e., data are self-reported and are based on current smoking habits, with little validation of amount, duration or type of exposure based on cigarette type. The surveys examined for the current analyses are wide-reaching, with many purposes; thus, the samples are not constructed specifically to include large numbers of smokers. In spite of combining data from multiple survey administrations, there are some instances of sparse data that preclude detailed analyses.

The strengths of these analyses include the use of multiple data sources, and thus the ability to compare results across surveys. Moreover, analyses are based on different samples, all intended to represent the U.S. population overall, and employ slightly different survey methods and questions that cover different years. Thus,

the differences in methods used by the different surveys would supply evidence of consistency, if consistency exists. The use of data from multiple administrations of each survey increases the precision of statistical estimates, and allows examination of the association between cigarette type and measures of dependence within strata defined by socio-demographic characteristics. Multivariable analyses control for characteristics associated with both cigarette type preference and features of smoking habit that might suggest differences in dependence.

In summary, findings from the current analyses that examine number of cigarettes smoked per day, time to first cigarette after waking and HSI, coupled with evidence from previous studies based on nationally representative populations do not support an evidence-based conclusion that menthol in cigarettes increases dependence among U.S. smokers. Results from the current analyses indicate that menthol smokers do not report smoking a greater number of cigarettes per day compared to non-menthol smokers; that the distribution of menthol compared to non-menthol smokers into categories of time to first cigarette after waking is nearly identical; and, that menthol smokers are generally more likely to be in a lower versus higher HSI (i.e., dependence) category.

Conflict of interest

Financial support for this work was provided through a contract between RAI Services Company (Winston-Salem, NC, USA) and ENVIRON International Corporation (Amherst, MA, USA). Sandra I. Sulsky and Cynthia Van Landingham are employees of ENVIRON International Corporation; Kristin M. Marano, Monica J. Graves, Michael W. Ogden, James E. Swauger and Geoffrey M. Curtin are employees of RAI Services Company.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.yrtph.2014.05.011.

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